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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,380	01/05/2004	Joseph Edward Zahner	NR 04-001	2953

7590 03/07/2006

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EXAMINER	
SCHLAPKOHL, WALTER	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/751,380	ZAHNER, JOSEPH EDWARD	
	Examiner	Art Unit	
	Walter Schlapkohl	1636	wdj

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-14* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 3-5, drawn to a polypeptide comprising SEQ ID NO: 7, classified in class 530, subclass 350.

II. Claims 1 and 3-5, drawn to a polypeptide comprising SEQ ID NO: 8, classified in class 530, subclass 350.

III. Claims 1 and 3-5, drawn to a polypeptide comprising SEQ ID NO: 9, classified in class 530, subclass 350.

IV. Claims 1 and 3-5, drawn to a polypeptide comprising SEQ ID NO: 10, classified in class 530, subclass 350.

V. Claims 1 and 3-5, drawn to a polypeptide comprising SEQ ID NO: 11, classified in class 530, subclass 350.

VI. Claims 1 and 3-5, drawn to a polypeptide comprising SEQ ID NO: 12, classified in class 530, subclass 350.

VII. Claims 1 and 3-5, drawn to a polypeptide comprising SEQ ID NO: 13, classified in class 530, subclass 350.

VIII. Claims 1 and 3-5, drawn to a polypeptide comprising SEQ ID NO: 14, classified in class 530, subclass 350.

IX. Claims 1 and 3-5, drawn to a polypeptide comprising SEQ ID NO: 15, classified in class 530, subclass 350.

X. Claims 1 and 3-5, drawn to a polypeptide comprising SEQ ID NO: 16, classified in class 530, subclass 350.

XI. Claims 1 and 3-5, drawn to a polypeptide comprising SEQ ID NO: 17, classified in class 530, subclass 350.

XII. Claims 1 and 3-5, drawn to a polypeptide comprising SEQ ID NO: 18, classified in class 530, subclass 350.

XI. Claims 1 and 3-5, drawn to a polypeptide comprising SEQ ID NO: 19, classified in class 530, subclass 350.

XII. Claims 1 and 3-5, drawn to a polypeptide comprising SEQ ID NO: 20, classified in class 530, subclass 350.

XIII. Claims 6-13, drawn to a polynucleotide in a vector and as they read on such a polynucleotide in a host cell in a transgenic animal and as they read on SEQ ID NO: 21, classified in class 800, subclass 13.

XIV. Claims 6-13, drawn to a polynucleotide in a vector and in a host cell as they read on such a polynucleotide in a host cell in a transgenic plant, a yeast cell, an insect cell and a mammalian cell and as they read on SEQ ID NO: 21, classified in class 536, subclass 23.4.

XV. Claims 12 and 14, drawn to a polynucleotide comprising a sequence set forth in SEQ ID NO: 25, classified in class 536, subclass 23.4.

Claim 2 link(s) inventions I-XII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 2. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d

1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Groups I-XII and Groups XIV-XV are comprised of multiple independent and/or distinct inventions recited in the alternative which are the products or methods drawn to different polypeptide/polynucleotide sequences which do not render obvious each other and thus are patentably distinct. Applicant must elect a single invention which is the product or method drawn to one specific polypeptide/polynucleotide sequence to which the claims will be restricted. Applicant must also indicate which claims are readable on the elected invention. This is not an election of species because the polypeptide/polynucleotide sequences are different and distinct. This restriction to examination of a single sequence is due to the now very high and undue burden for examining more than one sequence which is caused by the continued exponential increase in size of the sequence databases to be searched for each sequence, resulting in a corresponding increase in computer search time and examiner time for reviewing the computer search results. Therefore, the limited resources of the Office no longer permit examination of more than one sequence in an application.

Note: the non-standard format of this restriction, separating the inventions into multi-invention groups drawn to independent or distinct types of products, followed by an election of a single invention drawn to one sequence within the elected multi-invention group, was done for the sake of compactness of the communication and clarity, instead of using the more standard format setting forth each separate invention drawn to each separate sequence which would require a much longer communication.

The inventions are independent or distinct, each from the other because:

Inventions I-XII and Inventions XIII-XV are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the proteins of Groups I-XII and the polynucleotides of Groups XIII-XV are distinct inventions for the following reasons. Proteins, which are composed of amino acids and DNA sequences, which are composed of purine and

pyrimidine units, are structurally distinct molecules; any relationship between a protein and a DNA sequence is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded protein. In the instant case, for example, the claimed polynucleotides of Groups XIII-XV may be used to make some, but not all, of the polypeptides of Groups I-XII. Furthermore, while some of the Group I-XII polypeptides are encoded by some of the Group XIII-XV polynucleotides, the polypeptides of the Group I-XII claims could, for example, also be produced synthetically. For these reasons, the Group I-XII and Group XIII-XV inventions are patentably distinct.

Inventions XIV-XV and Invention XIII are also directed to related products. In the instant case, Invention XIII is distinct from Inventions XIV-XV because the inventions as claimed do not overlap in scope, i.e., are mutually exclusive: a transgenic animal host cell does not overlap in scope with a host cell of a transgenic plant, a yeast cell, a mammalian cell or an insect cell. Neither are host cells in a transgenic animal obvious variants over other types of host cells. Furthermore, the transgenic animal host cells comprising the claimed polynucleotides can have a materially different design, mode of operation, function, or effect.

Furthermore, searching the inventions of the Group I-XII, Group XIII, and Group XIV-XV claims together would impose a serious search burden. In the instant case, the search of the proteins and the nucleic acids are not coextensive, nor are the searches for the host cells comprising the polynucleotides of Group XIII and Group XIV-XV inventions. The inventions of Groups I-XII, Group XIII and Groups XIV-XV have a separate status in the art as shown by their different classification. In cases such as this one where descriptive sequences are provided, the sequences are searched in the appropriate databases. There is a search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the polynucleotide sequences of interest there may be journal article devoted solely to proteins, which would not have described the nucleic acid. Similarly, there may have been "classical" genetics papers which have no knowledge of the polypeptides, but spoke to the polynucloetides. Searching, therefore, is not coextensive.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Conclusion

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view

the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter A. Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office.)

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

February 21, 2006

NANCY VOGEL
PRIMARY EXAMINER